

EXHIBIT [3] -  
Laidlaw Expert  
Report  
(public document)

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

Victor VOE, et al.,

Plaintiffs,

v.

Case No. 1:23-cv-864

Thomas MANSFIELD, et al.,

Defendants,

Philip E. BERGER, et al.

Intervenor-Defendants

**EXPERT REPORT OF  
MICHAEL K. LAIDLAW, M.D.**

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I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. The information provided regarding my professional background is detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

4. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland disorders. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

5. I have been retained by Intervenor-Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment, including the trustworthiness of proposed standards of care or treatment guidelines promulgated by medical organizations.

6. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

7. I am being compensated at an hourly rate of \$500 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. I am being compensated at an hourly rate of \$750 for testimony at depositions or trial. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

8. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist in particular dealing with hormone excess, hormone deficiency, and hormone balance; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the

treatment of gender dysphoria, including for minors and adults; and (4) my first-hand personal experience in human research as a physician, having been involved in two studies, one involving magnesium and bone density and the other involving ultrasound use for detecting recurrent thyroid cancer.<sup>1</sup> I frequently review medical studies conducted by others and have experience assessing the strengths and weaknesses of such studies.

9. I was provided with and reviewed the following case-specific materials: the plaintiffs' complaint, House Bill 808, and the documents produced by the World Professional Association of Transgender Health (WPATH) and the United States Department of Health and Human Services (HHS).

10. A true and correct copy of my CV is attached to this declaration. In the previous four years, I have provided expert testimony in the following cases: *A.B. vs. Premera Blue Cross*, No. 2:23-cv-00953-TSZ (W.D. Wash. Filed June 27, 2023); *T.D. v. Wrigley*, No. 08-2023-CV-02189 (N.D. filed Sept. 14, 2023); *Brockman v. Kaiser Foundation Hospitals, Inc.*, No. STK-CV-UMM-2023-0001612 (Cal. Sup. Ct. filed Feb. 22, 2023); *Van Garderen v. State of Montana*, No. DV 2023-0541 (Missoula Cnty. Dist. Ct. filed May 9, 2023); *Koe v. Noggle*, No. 1:23-cv-02904-SEG (N.D. Ga. filed June 29, 2023); *Poe v. Drummond*, No. 23-cv-00177-JFH-SH (N.D. Okla. filed May 2, 2023); *Doe v. Thornbury*, No. 3:23-CV-00230-DJH (W.D. Ky. filed May 3, 2023); *L.W. v. Skrmetti*, No. 3:23-cv-00376 (M.D. Tenn. filed Apr. 20, 2023); *Boe v. Marshall*, No. 2:22-cv-184-LCB (M.D. Ala. filed Apr. 19, 2022); *Dekker v. Marstiller*, No. 4:22-cv-00325-RHMAF (N.D. Fla. filed Sept. 7, 2022); *C.P. v. Blue Cross Blue Shield of Illinois*, No. 3:20-cv-06145-RJB (W.D. Wash. filed Nov. 23, 2020); *Pflag, Inc. v. Abbott*, No. D-1-GN-22-002569 (459th Dist. Ct., Travis Cnty., filed June 8, 2022); *Paoli v. Hudson*, No. 279126 (Cal. Super. Ct. Tulare Cnty. filed June 20, 2019); *Doe v. Snyder*, No. 4:20-cv-00335-SHR (D. Ariz. filed Aug. 6, 2020); *A.M. v. Dr. F.*, No. S2011599, 2021 BCSC 32 (Can.); *A.B. v. C.D.*, [2019] No. E190334 (Can. B.C. Sup. Ct. J.); and *A.B. v. C.D.*, 2020 BCCA 11 (Can.).

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<sup>1</sup> For the latter study I helped to design an Institutional Review Board ("IRB") approved protocol. Furthermore, I received certification in the required course "Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research" at the University of Southern California in 2003.

11. In my professional opinion, treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution. Except in the case of a fatal injury or disease, the minor will become an adult and present to the adult physician. The adult physician must be able to have a thorough understanding of any condition which alters the biological development of children and, in the case of the endocrinologist, be knowledgeable about the long-term effects of hormones on the human body, particularly when the hormones are being used in ways that alter development.

12. The following expresses my expert opinion regarding minors who present with a disparity between their biological sex and internal feeling about their gender, specifically with regard to the use of social transition, medications which block normal pubertal development, the applications of hormones of the opposite sex, and surgical procedures that alter the genitalia and/or breasts for those individuals.

## **I. Background**

### **A. Biological Sex in Contrast to Gender Identity**

13. A recognition and understanding of biological sex is critical to my practice as an endocrinologist because the endocrine physiology of men and women, boys and girls, differ.

14. Biological sex is the objective physical condition of having organs and body parts which correspond to a binary sex. There are only two physical sexes, male and female. The male is identified as having organs and tissues such as the penis, testicles and scrotum. The female sex is identified by having organs and tissues such as the labia, vagina, uterus, and ovaries. Biological sex is easily identified by physical observation such that adults and even young children can identify the biological sex of a newborn baby.

15. It is also noteworthy that the physical organs described above as representing biological sex have a physical genetic correlate. In other words, it is a well-established scientific fact that two X chromosomes identify the cells correlating to a female person, and an X and a Y chromosome correlate to a male person.

16. Gender identity is not a component of sex. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR) states that “sex and sexual refer to the biological indicators of

male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitalia” (DSM-5 TR, emphasis added). Note that gender identity is not a component of biological sex as defined by the DSM 5.

17. Gender identity in the DSM 5 is defined separately: “Gender identity is a category of social identity and refers to an individual’s identification as male, female, or, occasionally, some category other than male or female” (DSM 5-TR). So, we can see that gender identity is not a physical entity but is described as a social identity. It is a subjective identification known only once a patient makes it known. It cannot be identified by any physical means, cannot be confirmed by any outside observer, and can change over time.

18. Gender identity is a psychological concept. It has no correlate in the human body. In the letter to the editor I wrote with my colleagues, we wrote in our critique of the Endocrine Society Guidelines that “[t]here are no laboratory, imaging, or other objective tests to diagnose a ‘true transgender’ child” (Laidlaw et al., 2019).

19. For example, one cannot do imaging of the human brain to find the gender identity. Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, genetic testing, or other biological markers that can identify the gender identity. There is no known gene that maps to gender identity or to gender dysphoria. In other words, there is no objective physical measure to identify either gender identity or gender dysphoria.

20. This is in contrast to endocrine disorders which have a measurable physical change in either hormone levels or gland structure which can be confirmed by physical testing. Therefore, gender dysphoria is a purely psychological phenomenon and not an endocrine disorder. But as my colleagues and I wrote in our letter to the editor, it becomes an endocrine condition through gender affirmative therapy: “Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDGS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy” (Laidlaw et al. 2019).

21. Gender identity is not determined by any known gene or set of genes. If gender identity were to be determined by genes, we would expect that identical twins would profess having the same gender identity nearly 100 percent of the time. This is not the case. In fact, the largest transsexual twin study ever conducted included seventy-four pairs of identical twins



(Diamond, 2013). They were studied to determine in how many cases both twins would grow up to identify as transgender. In only twenty-one of the seventy-four pairs (28 percent) did both identical twins identify as transgender. This is consistent with the fact that multiple factors play a role in determining gender identity, including psychological and social factors. This study suggests that those factors are more important than any potential genetic contribution. Furthermore, no genetic studies have ever identified a transgender gene or genes.

22. Sex is clearly identified in 99.98% of cases by chromosomal analysis (Sax, 2002). Sex is also clearly recognized at birth in 99.98% of cases (Id.). Therefore, sex is a clear provable objective reality that can be identified through advanced testing such as karyotyping, or simple genital identification at birth by any layperson. The other 0.02% of cases have some disorder of sexual development (DSD). DSDs do not represent an additional sex or sexes, but simply a disorder on the way to binary sex development (Chan et al., 2021).

## **B. Human Sexual Development**

### **1. Embryologic Development**

23. Another confirmation that there are only two biological sexes comes from what is known about embryologic development and fertilization. The biologic development of the human person begins with a gamete from a female termed an ovum or egg and a gamete from a biological male which is termed sperm. The fertilization of the egg by the sperm begins the process of human biological development. The cells of the fertilized ovum then multiply and the person undergoes the incredible changes of embryologic development.

24. It is noteworthy that the male sperm comes from the biological male and the female egg comes from the biological female. There is no other third or fourth or fifth type of gamete that exists to begin the development of the human person. This is consistent with the binary nature of human sex (Alberts et al., 2002).

25. The sex binary of the human embryo is further developed between roughly weeks 8 to 12 of human development. There are two primitive structures present within the developing embryo called the Wolffian duct and Mullerian ducts (Larsen et al., 2003). The Wolffian ducts develop into substructures of the genitalia including the vas deferens and epididymis which belong exclusively to the male sex. For the female, the Mullerian ducts go on to form the uterus, fallopian tubes, cervix and upper one third of the vagina which belong exclusively to the female sex (Id.)

26. Significantly once the male structures are developed from Wolffian ducts, the Mullerian ducts are obliterated. This means that throughout the rest of embryological development the Mullerian ducts will not form into biological female structures. Likewise, in the female, the Wolffian ducts are destroyed by week 12 and will not form male structures at any point in the future (Id.).

27. Thus we can see in very early development that the sex binary is imprinted physically not only in the chromosomes, but also on the very organs that the body produces. Additionally, the potential to develop organs of the opposite sex is eliminated. Thus, in the human being there are only two physical tracts that one may progress along, the one being male and the other being female (Wilson and Bruno, 2022).

## **2. Pubertal Development**

28. As mentioned previously, at the time of birth an infant's sex is easily identified through observation of the genitalia. Corresponding internal structures could also be confirmed through imaging if needed.

29. In early childhood, some low level of sex hormones are produced by the sex glands. The male testes produce testosterone. The female ovaries produce primarily the hormone estrogen. These sex glands remain quiescent for the most part, producing low levels of sex hormones until the time of pubertal development.

30. Puberty is an essential part of human development. Its purpose is to achieve full adult sexual function and reproductive capacity. Puberty is a time of development of the sex organs, body, and brain. There are well known changes in physical characteristics of the male such as growth of facial hair, deepening of the voice, and increasing size of the testicles and penis. Importantly, the testicles will develop sperm under the influence of testosterone and become capable of ejaculation. Because of these changes, the male will become capable of fertilizing an egg. The inability to produce sperm sufficient to fertilize an egg is termed infertility.

31. For the female, pubertal development includes changes such as breast development, widening of the pelvis, and menstruation. The female will also begin the process of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs from the ovary. Once the eggs are released in a manner in which they can become fertilized by human sperm then the female is termed fertile. The inability to release ovum that can be fertilized is infertility (Kuohong and Hornstein, 2021).

### **3. Tanner Stages of Development**

32. From a medical perspective it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development. Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system which will allow the stage of puberty to be known.

33. Tanner stages are divided into five. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

34. Awareness of the Tanner stage of the developing adolescent is also useful to assess for maturation of sex organ development leading to fertility. For girls, the first menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). For males, the first appearance of sperm (spermarche) will typically be Tanner stages 4 (Id.). If puberty is blocked or disrupted before reaching these critical stages, the sex glands will be locked in a premature state and incapable of fertility.

### **4. Biological Sex Cannot Be Changed**

35. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

36. Furthermore, as noted earlier, several of the sex specific structures (such as the epididymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to resuscitate these ducts and continue development of opposite sex structures.

37. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm

capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

38. In fact, as I will discuss, gender affirming therapy can lead to infertility and potential sterilization.

### **C. Endocrine Disorders**

39. Before discussing gender dysphoria and gender affirmative therapy from the perspective of an endocrinologist, it is helpful to discuss the background of endocrine diseases. This background demonstrates the difference in gender dysphoria, which is a psychological diagnosis, and other conditions treated by endocrinologists, which are physical diagnoses.

40. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided into three main types: those that involve hormone excess, those that involve hormone deficiency, and those that involve structural abnormalities of the glands such as cancers.

41. It is important for the endocrinologist to determine the cause of hormone gland excess or deficiency in order to devise an appropriate treatment plan. The plan will generally be to help bring the hormones back into balance and thus bring the patient back to health.

42. To give an example of hormone excess, hyperthyroidism is a term which means overactivity of the thyroid gland. In this condition excess thyroid hormone is produced by the thyroid gland. This results in various physical and psychological changes for the afflicted patient. Examples of physical changes can include tachycardia or fast heart rate, hand tremors, and weight loss. Examples of psychological symptoms include anxiety, panic attacks, and sometimes even psychosis.

43. An endocrinologist can recognize thyroid hormone excess in part by signs and symptoms but can also confirm the diagnosis with laboratory testing that shows the thyroid hormones to be out of balance. Once this is determined and the degree of excess is known, then treatments can be given to bring these levels back into balance to benefit the patient's health and to prevent other disease effects caused by excess hormone.

44. To give another example, consider a deficiency of insulin. Insulin is a hormone which regulates blood glucose levels. If there is damage to the pancreas such that insulin levels are very low, then blood glucose levels will rise. If the glucose levels rise to a certain abnormally high level, then this is considered diabetes. In the case of type 1 diabetes, insulin levels are abnormally low and therefore blood glucose levels are abnormally high leading to a variety of

signs and symptoms. For example, the patient may have extreme thirst, frequent urination, muscle wasting, and weight loss. They may often experience lethargy and weakness.

45. In this case laboratory tests of glucose and insulin levels can confirm the diagnosis. Once diabetes is confirmed, the patient is then treated with insulin to help restore glucose balance in the body and prevent long-term complications of diabetes.

46. To give an example of a structural abnormality, a patient may have a lump on the thyroid gland in the neck. This may be further examined by an imaging test such as an ultrasound. A needle biopsy can be performed so that the cells can be examined under a microscope. A trained medical professional such as a pathologist can then examine the cells to determine if they are benign or cancerous. In the case of thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

47. Noteworthy in the preceding three examples is that all three disease conditions are diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging test of an organ, or an examination of cells under a microscope—or all three—may be employed in the diagnosis of endocrine disease.

#### **D. Gender Dysphoria is a Psychological Diagnosis**

48. Gender dysphoria, on the other hand, is not an endocrine diagnosis. It is a psychological diagnosis. Gender dysphoria is the persistent state of distress that stems from the feeling that one's gender identity does not align with one's physical sex (DSM-5 TR). It is diagnosed purely by psychological methods of behavioral observation and questioning. The criteria for diagnosis is found in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR).

49. As a practicing endocrinologist and scientist, I have made a study of GD and its treatment for two reasons: 1) I want to be sure that my colleagues and I understand the science before we treat any patients with GD; and 2) I am concerned that the medical society that claims to speak for me and other endocrinologists has abandoned scientific principles in endorsing treatments for GD that have questionable scientific support. The opinions expressed in this report are the result of my own experience, studies, education, and review of the scientific literature related to GD.

## **II. Gender Affirmative Therapy**

50. In the section that follows I discuss four interventions (social transition, blocking normal puberty, opposite sex hormones, and surgery) that some physicians are using to treat gender dysphoria. Each intervention can lead to iatrogenic harms to the patient. The term “iatrogenic” is used in medicine to describe harms or newly created medical conditions that are the result of a treatment. These harms will be described in detail below. I speak of these harms because it is important to understand that once a patient begins GAT it is more likely the patient will continue on to surgery (de Vries et al., 2011; de Vries et al., 2014). Thus, GAT interrupts the natural desistance process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist: if I did not understand these harms, I could not advise patients of the risks associated with GAT.

51. There are three general approaches to treating gender dysphoria in minors. (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal sense of gender with their physical sex. Another would be to “watch and wait” and allow time and maturity to help the young person align sex and gender through natural desistance, while providing psychological support and therapy as needed and addressing comorbidities. The third option, which is the focus of that which follows, is referred to as gender affirmative therapy.

52. Gender affirmative therapy of adults and minors consists of psychosocial, medical, and surgical interventions that attempt to psychologically and medically alter the patient so that they come to believe they may become similar to the physical sex which aligns with their gender identity (but not their biological sex) and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

53. The application of this medical therapy to minors<sup>2</sup> is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suffers from a lack of a

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<sup>2</sup> “[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age. Additionally, *Bright Futures* guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age, dividing the group into early (ages 11–14 years), middle (ages 15–17 years), and late (ages 18–21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988, which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in

quality evidence-base, poorly performed studies, and ongoing unethical human experimentation. As discussed below, in my professional opinion as an endocrinologist, no child should be given these treatments.

#### **A. Social transition**

54. The first stage of gender affirmative therapy is termed social transition. Social transition is a psychological intervention. The child may be encouraged to adopt the type of clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a culture. For example, in the United States a boy might wear his hair long and wear dresses to socially transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

55. Social transition of the child has been noted by an expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex. The 2017 Endocrine Society Guideline states that "[s]ocial transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence" (Hembree et al., 2017). A recent study also supports the contention that children who undergo social transition are more likely to have their gender dysphoria persist into adolescence. In the 2022 article "Gender Identity 5 Years After Social Transition," which studied 317 socially transitioned youths, the authors found that "most participants were living as binary transgender youth (94.0%)" (Olson et al., 2022).

56. From an endocrine point of view, it is understandable that a child having the outward appearance of the opposite sex would believe that he or she is destined to go through puberty of the opposite sex. At this age, the child likely has only a poor understanding of the internal structures of the body, the function of the sex glands, the role of the sex glands in fertility and so forth.

57. Therefore, it would be quite frightening for a boy who believes he is a girl to be turning into a man with all of the adult features that accompany manhood. Vice versa, the girl who

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the case of a child with special health care needs. Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life." (Hardin, 2017) (footnotes omitted).

has become convinced that she is a boy will be frightened by the physical changes brought on by womanhood.

58. In fact, it would appear that in the minds of children and adolescents that they are anticipating a sort of disease state in the future by the hormone changes that will occur as a normal and natural part of human development. Until relatively recently in human history, it has not been possible to interfere with puberty through pharmaceutical means.

## **B. Medications That Block Pubertal Development**

### **1. Background**

59. A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications (PB) that act directly on the pituitary to cause the endocrine condition known as hypogonadotropic hypogonadism (HH).

60. In order to understand what is occurring in this process, it is helpful to be aware of normal hormone function during pubertal development. There is a small pea-sized gland in the brain called the pituitary. It is sometimes referred to as the “master gland,” as it controls the function of several other glands. One key function for our purposes is the control of the sex glands. There are two specific hormones produced by the pituitary referred to as luteinizing hormone (LH) and follicle stimulating hormone (FSH). These are responsible for sex hormone production and fertility. The LH and FSH act as signals to tell the sex glands to begin or to continue their function.

61. In the adult male, the production of LH will cause adult levels of testosterone to be produced by the testicles. In the adult female, the production of LH will cause adult levels of estrogen to be produced by the ovaries.

62. In early childhood, prior to the beginning of puberty, the pituitary function with respect to the sex glands is quiescent. However, during pubertal development LH will signal the testicle to increase testosterone production and this carries the boy through the stages of pubertal development into manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen production and carries the girl through the stages of development into womanhood.

63. Hypogonadotropic hypogonadism is a medical condition in which the pituitary does not send the hormonal signals (LH and FSH) to the sex glands. Therefore, the sex glands are unable to make their sex specific hormones of testosterone or estrogen.



64. If this condition occurs during puberty, the effect will be to stop pubertal development. This is a disease state which is diagnosed and treated by the endocrinologist.

65. Medications such as GnRH analogues (sometimes called puberty blockers) act on the pituitary gland to lower the pituitary release of LH and FSH levels dramatically. The result is a blockage of the signaling of the pituitary to the testicles or ovaries and therefore underproduction of the sex hormones. This will stop normal menstrual function for the female and halt further pubertal development. For the male this will halt further pubertal development. If the male had already reached spermatarche, then production of new sperm will stop.

## **2. GnRH Agonist Medication Effects Vary by Use Case**

66. There are a variety of uses for GnRH agonists. The use and outcome can be very different for different applications.

67. For example, the initial development of the medication called Lupron was for the treatment of prostate cancer, the idea being that blocking pituitary hormones will block the adult male's release of testosterone from the testicles. Since testosterone will promote the growth of prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent the growth and spread of prostate cancer. This is a labeled use of the medication. In other words, there is FDA approval for this use.

68. Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is activated at an abnormally young age<sup>3</sup>, say age four, to begin pubertal development. In order to halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. Here the action of the medication on the pituitary will disrupt the signaling to the sex glands, stop early sex hormone production, and therefore stop abnormal pubertal development.

69. Then, at a more normal time of pubertal development, say age 11, the medication is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland function and timing of puberty. This is a labeled use for a GnRH agonist medication.

70. What about the use of GnRH analogue medications such as Lupron in gender affirmative therapy? In these cases, we have physiologically normal children who are just beginning puberty or are somewhere in the process of pubertal development. They have healthy

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<sup>3</sup> "The traditional definition of precocious puberty is the development of secondary sexual characteristics before 8 years of age in girls and 9 years in boys" (Kota and Ejaz, 2023).

pituitary glands and sex organs. However, a puberty blocking medication is administered to stop normal pubertal development.

71. In this case the condition of hypogonadotropic hypogonadism described above (a medical disease) is induced by medication and is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case.

72. In my opinion, there is not sufficient evidence to conclude that the use of puberty blockers to block natural puberty is safe when administered as part of gender affirming therapy. Nor is there sufficient evidence to conclude that the effects of puberty blockers when used in this manner are reversible.

### **3. Hypogonadotropic Hypogonadism**

73. As described above, hypogonadotropic hypogonadism is a condition in which the pituitary fails to send signals to the gonads thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

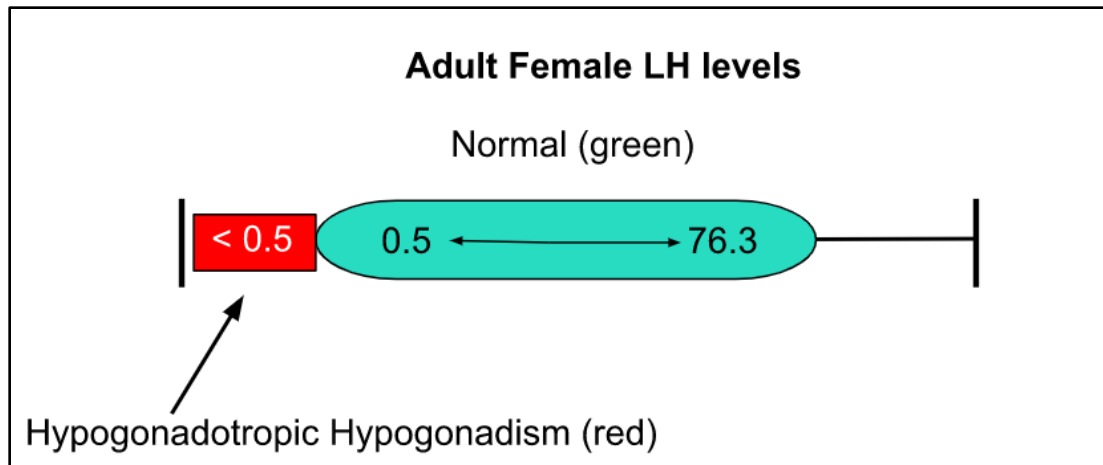
74. As an endocrinologist I frequently evaluate patients to ascertain if they have the condition of hypogonadotropic hypogonadism. This is done by a laboratory evaluation. If the patient has this condition, I then determine the cause and the proper treatment.

75. The primary hormone of the pituitary which is abnormal in this condition is called luteinizing hormone or LH. In order to diagnose the condition, a laboratory test with reference ranges based on the person's sex and age is used to evaluate the blood sample.

76. For example, figure 1 shows the normal laboratory reference range for LH over the course of a month in an adult pre-menopausal female (0.5-76.3 mIU/mL) (Quest LH, 2023). A very low level of LH (red) with low estrogen levels indicates hypogonadotropic hypogonadism<sup>4</sup>.

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<sup>4</sup> Levels will be similarly low for adolescents, though the normal reference range is different.



**Figure 1.**

77. As one can see, in hypogonadotropic hypogonadism the level of LH is below the reference range. In the female, this causes the cessation of estrogen production, and in the male it causes cessation of testosterone production. In adolescents of either sex, this will stop further pubertal development. For females in mid-puberty or beyond, this condition will also stop normal menstrual cycles and ovulation. For the male in mid-puberty or beyond, it will cause the cessation of normal sperm production.

78. As an endocrinologist, I would confirm the condition of hypogonadotropic hypogonadism based on laboratory results and then treat this medical condition.

79. What occurs to pituitary hormones and the sex hormones<sup>5</sup> when administering a GnRH analogue medication such as Lupron? The effect is identical to figure 1. Over time, the result of the medication is to cause very low LH levels (red) leading to low sex hormone levels thereby medically inducing the condition of hypogonadotropic hypogonadism.

80. In gender affirmative therapy, the medical condition of hypogonadotropic hypogonadism is being deliberately created by the use of medications called GnRH analogues, one of which is called Lupron.

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<sup>5</sup> The primary sex hormones being estrogen for females and testosterone for males.

#### **4. Adverse Health Consequences of Blocking Normal Puberty**

##### **a. Infertility**

81. There are a number of serious health consequences that occur as the result of blocking normal puberty. The first problem is infertility.

82. GnRHa have profound implications for fertility. The Endocrine Society Guideline recommends beginning puberty blockers as early as Tanner stage 2. As discussed earlier, this is the very beginning of puberty. Fertility development happens later, generally in Tanner stage 4. Thus, if the developing person is blocked at Tanner stage 2 or 3, as advocated by the guidelines, this is prior to the patient becoming fertile. The gonads will remain in an immature, undeveloped state.

83. If the patient remains blocked in an early pubertal stage, then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high doses of opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly, the removal of the gonads by surgery will ensure sterilization.

84. In a Dutch study by de Vries et al. that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization<sup>6</sup>. This is why puberty blockers, rather than being a “pause” to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries and potentially sterilizing hormonal treatments.

85. Even though procedures to preserve fertility are available for patients in late pubertal stages (Tanner 4 and 5), studies show that less than 5% of adolescents in North America receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), “ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental<sup>7</sup>.

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<sup>6</sup> The surgeries were consequential in another important way. One person who had a vaginoplasty died of post-surgical complications of necrotizing fasciitis which is a rapidly progressive and very severe infection of the soft tissues beneath the skin and which has a high mortality (Id.).

<sup>7</sup> “Once testicular tissue has been cryopreserved, future options for its use may include in vitro maturation or germ cell transplant, which at this time are theoretical in nature” (Klipstein et al., 2020).

These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child” (Laidlaw, Cretella, et al., 2019).

86. As an example, if a four-year-old child is diagnosed with precocious puberty, the abnormally early puberty may be halted by GnRH analogues (puberty blocking medication). The child will at a later time, say at age 12, have the puberty blocker discontinued and at that point normal pubertal development will be allowed to proceed. Therefore, when the child is no longer taking the medication, he or she will gain natural fertility.

87. In contrast, puberty blocking medication given to minors as a part of GAT occurs during the time for natural puberty—precisely the time that the adolescent person would have otherwise gained reproductive function. The effects of puberty blockers on the adolescent are to prevent sperm production in the male and ovulation in the female, which produces the infertile condition. Importantly, so long as the minor continues PB, he or she will thus remain infertile. And should the patient continue on to opposite sex hormones as part of GAT, then the patient will remain infertile. There is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility.

#### **b. Sexual Dysfunction**

88. Another problem I would expect to find in youths who have HH and puberty stopped at an early stage is sexual dysfunction. The child will continue their chronological age progression toward adulthood and yet remain with undeveloped genitalia. This will lead to sexual dysfunction, including potential erectile dysfunction and inability to ejaculate and orgasm for the male. For the female with undeveloped genitalia potential sexual dysfunction may include painful intercourse and impairment of orgasm.

89. An example of the impairment of sexual function caused by stopping puberty in early development was evident in the TLC reality show “I am Jazz”. This program documents Jazz Jennings’s life experiences as a person with gender incongruence including Jazz’s medical care. Jazz had been given puberty blockers at an early pubertal stage. In an episode of the show, Jazz, who was identified as a male at birth, visited the plastic surgeon, Christine McGinn, for a surgical evaluation for genital surgery (TLC, accessed 2022). Dr. McGinn describes her evaluation of Jazz’s penis, stating it is “very, very small”. In my opinion this very small penis size is consistent with beginning puberty blockers at a very early pubertal stage. Jazz also has a discussion about

sexual function with the surgeon. Jazz states: “I haven’t experienced any sexual sensation.” Regarding orgasm, Jazz says: “I don’t know, I haven’t experienced it”<sup>8</sup> In my opinion, these descriptions are consistent with the type of sexual dysfunction that one would expect from early blockade of normal puberty.

**c. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density**

90. Puberty is a time of rapid bone development. This time period is critical in attaining what we call peak bone density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019).

91. Any abnormal lowering of sex hormones occurring during this critical time will stop the rapid accumulation of bone and therefore lower ultimate adult bone density. If a person does not achieve peak bone density, they would be expected to be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older patient very significantly increase the risk of major morbidity and death (Bentler, 2009). Allowing a “pause” in puberty for any period of time can lead to an inability to attain peak bone density.

92. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. In my practice I order and interpret DEXA scans for this purpose.

93. The Z-score of a DEXA scan is used to compare a patient’s bone density to the same population based on age and sex. For example, a person who has a bone density similar to the average of the population would be at the 50th percentile. Those who have greater relative bone density would be above the 50th percentile. Those who have lower bone density would have a Z score below the 50th percentile.

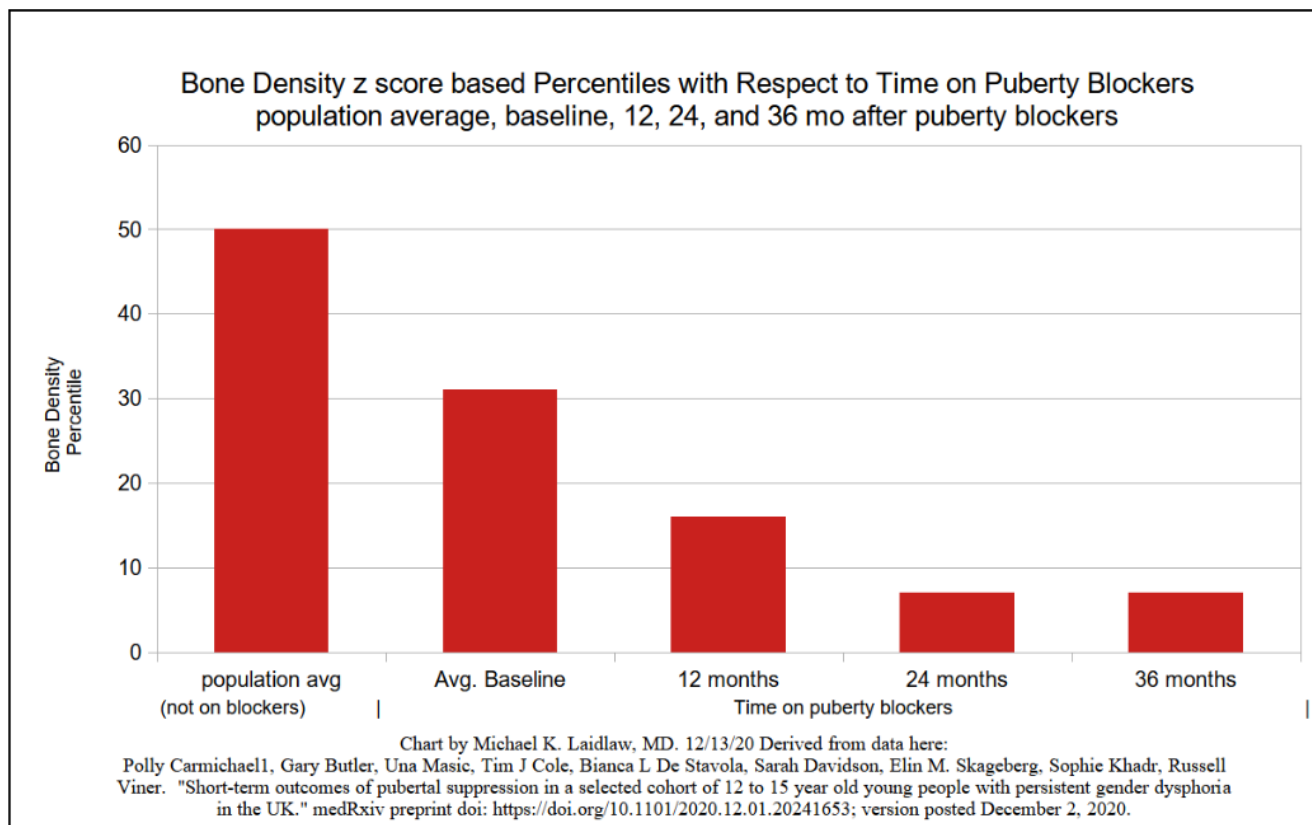
94. Puberty blockers used in adolescence to cause HH will inhibit the normal accrual of bone density. This can be evaluated by DEXA scan. In a study in the UK, 44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months (Carmichael, 2021).

95. Figure 2 shows the Z-scores of the average age matched population percentile which is 50%. It shows the average baseline (before puberty blockers) Z-score percentile for the study participants. It also shows the bone density percentile at 12, 24, and 36 months. One can see that the average baseline z score was about 32% compared to peers of similar age and sex. At 12

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<sup>8</sup> Jazz’s age is somewhere in the mid-teens during this episode.

months this had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers and remained at this low level.



**Figure 2**

96. This is the same pattern of diminishing bone density compared to their peers that one would see in hypogonadotropic hypogonadism due to a pituitary injury. However, in these cases hypogonadotropic hypogonadism was caused by GnRH analogues (puberty blocking medication) that lead to greatly diminished bone density compared to their peers of the same age.

97. In natal females, hypogonadotropic hypogonadism leads to amenorrhea, meaning the absence of menstrual periods. Amenorrhea is detrimental to bone health: “In addition to this<sup>9</sup> important long-term consequence of amenorrhea, other problems, such as premature bone demineralization or inadequate bone formation, are likely to put amenorrheic women at high risk for osteoporosis and fracture” (Santoro, 2011) (emphasis added).

<sup>9</sup> “This” refers to cardiovascular disease: “Diagnosis and treatment of amenorrheic states is of increasing clinical importance because lifetime menstrual irregularities are known to be predictive of subsequent CVD in women.”

98. Another consideration is the effects of HH in adolescents and late teens on the maturation of the human brain. It is known that adolescence is a crucial time of neurodevelopment and that puberty plays "a critical role in these neurodevelopmental processes" (Baxendale, 2024). Furthermore, "sex hormones including estrogen, progesterone, and testosterone can influence the development and maturation of the adolescent brain." (Arain, 2013). It is also known that the "suppression of puberty impacts brain structure and the development of social and cognitive functions in mammals, the effects are complex and often sex specific." (Baxendale, 2024). Therefore, there are unknown, but likely negative, consequences to blocking normal puberty with respect to brain development.

#### **d. Psychosocial Development**

99. A third major problem with blocking normal puberty involves psychosocial development. Adolescence is a critical time of physical, mental, and emotional changes for the adolescent. It is important that they develop socially in conjunction with their peers.

100. While I am not a psychologist, I am familiar with and rely upon the literature in this area for the rationale of the treatment of precocious puberty<sup>10</sup>. It is generally accepted in endocrinology that there are psychological benefits to adolescents who go through puberty around the same time as their peers, and this is why puberty blockers (GnRH analogues) in central precocious puberty are sometimes used to delay a child's abnormally early pubertal development to a more age-appropriate time.

101. The development of the adolescent along with their peers is also well recognized in the psychological literature: "For decades, scholars have pointed to peer relationships as one of the most important features of adolescence." (Brown, 2009). If one is left behind for several years under the impression that they are awaiting opposite sex puberty, they will miss important opportunities for socialization and psychological development. Psychosocial development will be necessarily stunted as they are not developing with their peers. This is a permanent harm as the time cannot be regained.

102. Aside from the multiple serious problems that are iatrogenically acquired by blocking normal puberty, there appear to be independent risks of the puberty blocking medication themselves. For example, one can read the labeling of a common puberty blocking medication

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<sup>10</sup> "The other concern often used as a rationale for treatment is negative psychosocial consequences of precocious puberty, particularly in girls" (Eugster, 2019, emphasis added).



called Lupron Depot-Ped and find under psychiatric disorders: “emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression” (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria (Kaltiala-Heino, 2015).

### **C. Opposite Sex Hormones**

103. The third stage of gender affirmative therapy involves using hormones of the opposite sex (also called cross sex hormones) at high doses to attempt to create secondary sex characteristics in the person’s body.

104. In GAT, what is termed “cross sex hormones” is the use of hormones of the opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these hormones are administered. When hormone levels climb above normal levels they are termed supraphysiologic.

#### **1. Testosterone**

105. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule 3 controlled substance by the DEA: “Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence” (DEA, 2022). A licensed physician with a valid DEA registration is required to prescribe testosterone.

106. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood, sexual function, libido, and bone density. Prescription testosterone is given to correct the abnormally low levels and bring them back into balance. The dose of testosterone must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone. The use of high dose testosterone in females is experimental.

107. Contrast the FDA approved use of testosterone in males versus its experimental use females. Testosterone is FDA approved for use in adult men as well as the pediatric male population aged 12 and older (Actavis, 2018). There is no FDA approved usage of testosterone for

women or pediatric aged females.<sup>11</sup> The prescribing indications for adult males and pediatric males are identical and are to treat the conditions of low testosterone caused by either primary hypogonadism or secondary hypogonadism (Id.). The intent of testosterone for women and pediatric aged females in GAT is to cause severe hyperandrogenism. In this case the purpose, effects, and ultimate outcome of the FDA approved usage of testosterone for males versus the experimental use for females in GAT are very different. Therefore, the low-quality evidence guidelines of the Endocrine Society/WPATH are not an acceptable substitute for proper scientific studies including randomized controlled trials (Malone et al., 2021; Hembree et al., 2017).

108. Regarding the potential for abuse, the labeling for testosterone reads: “Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication...Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions...Abuse and misuse of testosterone are seen in male and female adults and adolescents...There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice.” (Actavis Pharma, 2018, emphasis added)

109. Adverse events with respect to the nervous system include: “Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.” (Actavis Pharm, 2018)

110. With regard to ultimate height, “[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth” (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been.

111. With respect to the cardiovascular system of men using ordinary doses, “Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men” (Actavis Pharma, 2018). No clinical safety trials have been performed for women or adolescent girls to my knowledge.

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<sup>11</sup> “Testosterone Cypionate Injection, USP is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone” (Actavis, 2018, emphasis added).

112. “There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the leg] and pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using testosterone products, such as testosterone cypionate” (Actavis Pharma, 2018).

113. A very recently published study of adverse drug reactions (ADRs) as part of gender affirming hormone therapies in France states that “[o]ur data show a previously unreported, non-negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years... In transgender men taking testosterone enanthate, all reported ADRs were cardiovascular events, with pulmonary embolism in 50% of cases” (Yelehe et al., 2022).

114. There are also serious concerns regarding liver dysfunction: “Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications” (Actavis Pharma, 2018).

#### **a. Hyperandrogenism**

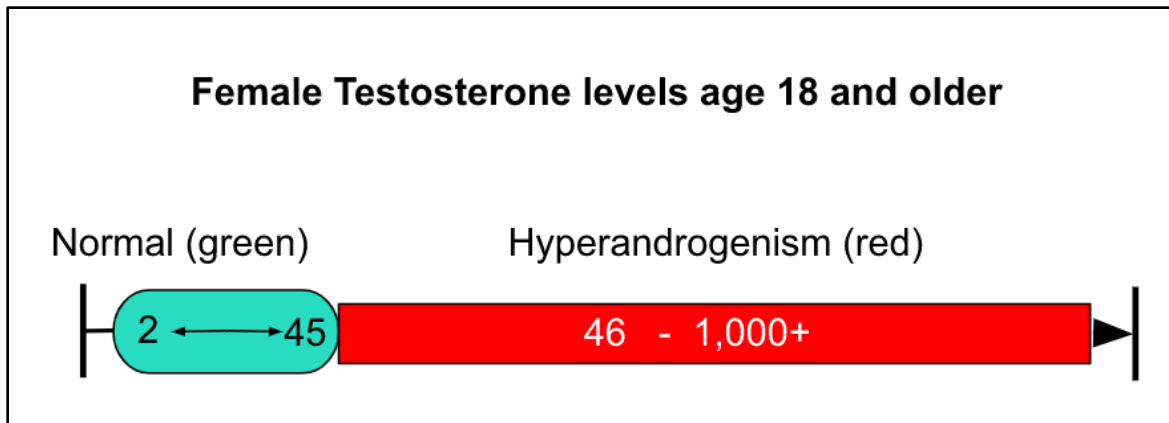
115. Hyperandrogenism is a medical condition of elevated blood androgens such as testosterone. As an endocrinologist I frequently evaluate patients to determine if they have the condition of hyperandrogenism. Hyperandrogenism in the female or male is harmful and can lead to various maladies.

116. In order to diagnose hyperandrogenism, a laboratory blood test of testosterone is done. In hyperandrogenism, one will find testosterone levels elevated above the reference range.

117. For example, for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).<sup>12</sup> However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

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<sup>12</sup> For females aged 11-17 the reference range is  $\leq 40$  and below this age group, the range is even lower.



**Figure 3**

118. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL.

119. I frequently diagnose and treat the hyperandrogen condition called polycystic ovarian syndrome (PCOS). These patients have elevated testosterone levels. These levels are mildly to moderately elevated and may range from 50-150. Hyperandrogenism found in PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

120. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause severely elevated testosterone levels in the 300-1000 range. Once the cause of a hyperandrogen condition is identified, treatments may be put in place to help bring the testosterone levels down to the normal reference range.

121. Recommendations from the Endocrine Society's clinical guidelines related to GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL<sup>13</sup> which is on the same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A simple

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<sup>13</sup> In the Endocrine Society's Guidelines there is no grading of evidence for the rationale of using such high supraphysiologic doses of opposite sex hormones for the female or male. There seems to be an underlying assumption that because the person believes to be the opposite sex then they acquire the sex specific laboratory ranges of the opposite sex. "The root cause of this flaw in thinking about diagnostic ranges was exemplified in a response letter by Rosenthal et al claiming that gender identity determines the ideal physiologic range of cross-sex hormone levels (5). Thus, a psychological construct, the 'gender identity', is imagined to affect physical reality and change a person's sex-specific laboratory reference ranges. This is clearly not the case, otherwise there would be no serious complications of high-dose androgen treatment in transgender males" (Laidlaw et al., 2021).

calculation shows this level for the adult may be anywhere from 6 to 100 times higher than native female testosterone levels. In doing so they are inducing severe hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

122. The following chart shows testosterone levels in the normal adult female range (blue), PCOS (gray), endocrine tumors (red), and gender affirmative therapy (orange) as part of female to male (FtM) transition (figure 4).

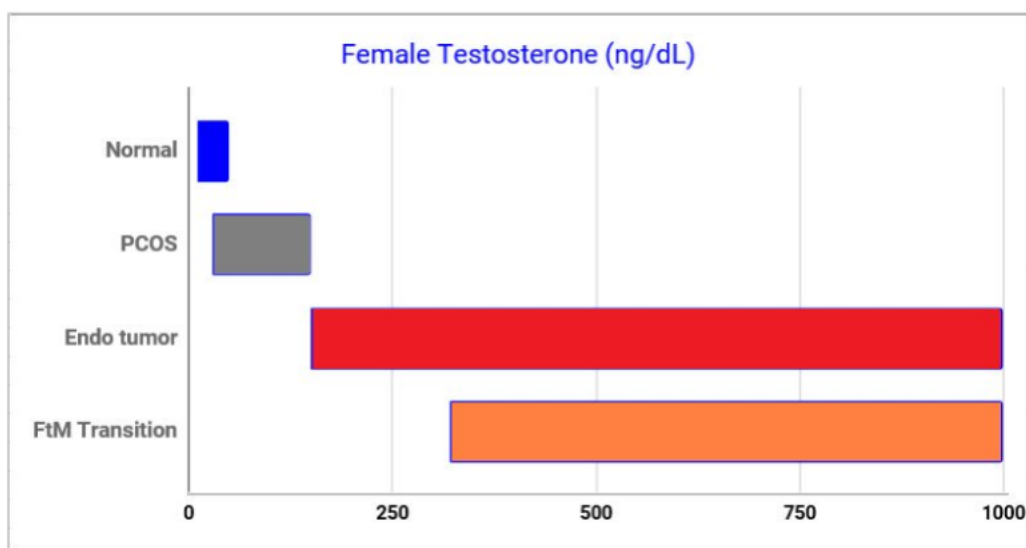


Image by Michael K Laidlaw, MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations of the Endocrine Society/WPATH are to bring levels into the 300-1000 range which is 6-100 times higher than normal endogenous adult female levels.

**Figure 4.**

#### **b. Medical Problems Related to Hyperandrogenism**

123. With respect to cardiovascular risk, “[s]tudies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone” (Laidlaw et al., 2021; Alzahrani et al., 2019).

124. Permanent physical effects of testosterone therapy involve irreversible changes to the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen, back and other areas is known as hirsutism. Should the female eventually regret her decision to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the scalp may also occur. I would expect these changes to occur to the plaintiffs taking testosterone to induce

hyperandrogenism. Common sense suggests that changes of voice and hair growth could be psychologically troubling should a patient decide to detransition and attempt to reintegrate into society as female.

125. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina (Hembree, 2017). The breasts have been shown to have an increase in fibrous breast tissue and a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017). I would expect some or all of these effects and risks to occur to the plaintiffs taking testosterone to induce hyperandrogenism.

126. The long-term effects of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones on ultimate sterility are unknown in the sense that we do not have studies showing precisely what happens, but based on what we do know, it seems safe to say that opposite sex hormones are likely cytotoxic to the immature gonads.

127. According to research, anabolic steroid abuse<sup>14</sup> has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The “most prominent psychiatric features associated with AAS [anabolic androgenic steroids, i.e., testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states” (Hall, 2005). Moreover, “[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms” (Hall, 2005).

128. In an observational study of the Food and Drug Administration’s Event Reporting system database for people using opposite sex hormones for the purpose of gender transition a “striking 88% were categorized as serious ADRs [adverse drug reactions]” (Gomez-Lumbreras and Villa-Zapata, 2024). Of natal females taking testosterone for transition, they found that “a substantial portion of the reports were deemed serious (72, 87.8%), with 2 deaths (2.4%) and 25

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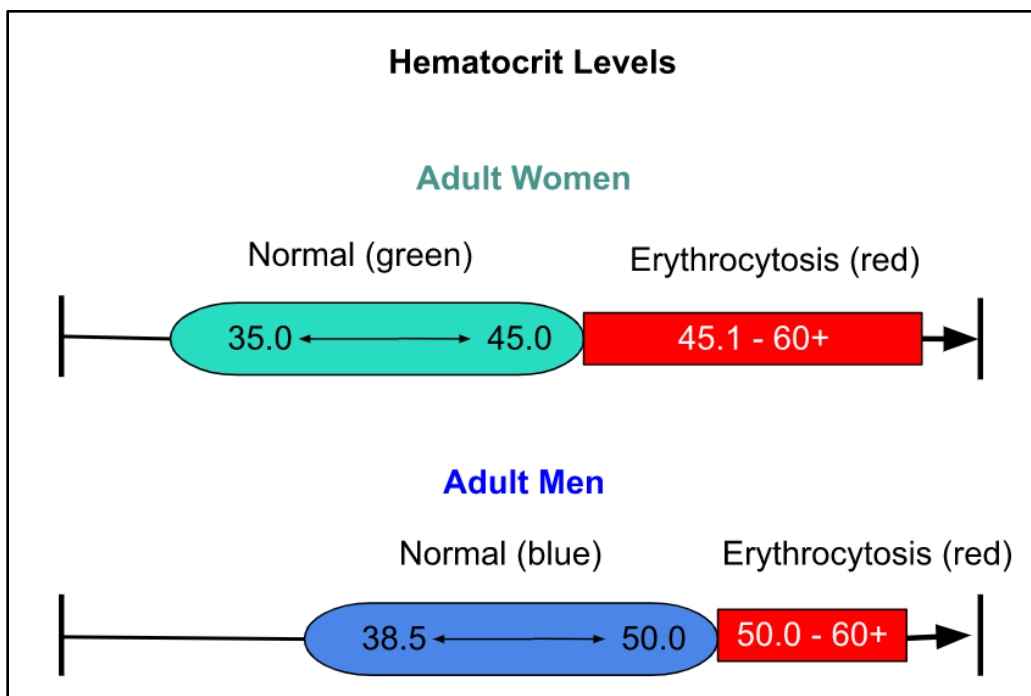
<sup>14</sup> Anabolic steroid abuse involves the deliberate creation of hyperandrogenism in the body as a result of high doses of testosterone or other androgens.

hospitalizations (30.5%)”. These serious findings of harm underscore the dangers of high dose testosterone used for the purpose of gender transition. With respect to psychological effects, adverse reactions included anxiety, depression, affect lability, euphoric mood, self-destructive behavior, anger, aggression, anti-social behavior, and homicidal ideation. Additionally, there were reports of suicide attempts, suicidal behavior and ideation, dissociation, and emotional disorder and distress. In my opinion, these adverse mental health findings of natal females on supraphysiologic doses of testosterone are consistent with the next closest biological model, which is anabolic steroid abuse.

### c. Erythrocytosis as a Result of Hyperandrogenism

129. I regularly monitor patients who are receiving testosterone to evaluate for erythrocytosis. Erythrocytosis is a condition of high red blood cell counts. Prolonged hyperandrogenism such as occurs with the use of testosterone at supraphysiologic levels can cause erythrocytosis.

130. Males and females have different reference ranges for red blood cells (measured as hematocrit). For example, the normal range of hematocrit for females over age 18 is 35.0-45.0% and males 38.5-50.0% (Quest Hematocrit, 2023). Levels above this range signify erythrocytosis (see figure 5).



### **Figure 5.**

131. As one can see, there is an overlap in the ranges of males and females such that levels between 45.1 and 50 are considered normal for the male. However, for the female these levels are considered erythrocytotic. Levels above 50 for the male are considered erythrocytosis and for the female severe erythrocytosis.

132. The Madsen study was a “20-year follow-up study in [1,073] adult trans men who started testosterone therapy and had monitoring of hematocrit at our center” (Madsen, 2021). In this study, 24% of trans men had hematocrit levels 50% at some time which would be considered severe erythrocytosis. Unfortunately, they did not examine the hematocrit range of 45-50. However, one would presume that this would occur in at least the same percentage or higher as those who had developed severe erythrocytosis.

133. Any level of erythrocytosis in young women has been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

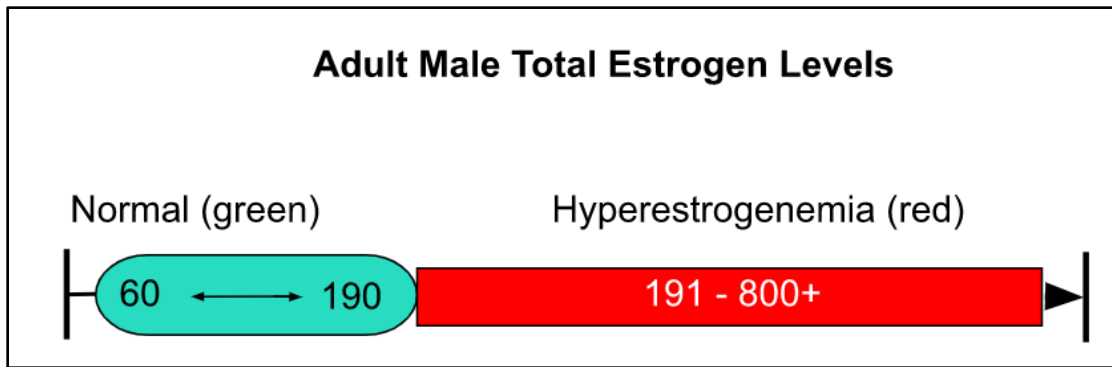
### **2. Estrogen**

134. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient’s age. Another labeled use of estrogen is to treat menopausal symptoms. The use of estrogen to treat pediatric age males is experimental.

135. Hyperestrogenemia is a condition of elevated blood estrogens such as estradiol. I regularly evaluate patients for hyperestrogenemia in my practice. Hyperestrogenemia in the male is harmful and can lead to various maladies.

136. In order to diagnose hyperestrogenemia, a laboratory blood test of estrogen is performed. In hyperestrogenemia, one will find estrogen levels elevated above the reference range. For example, in an adult male the normal estrogen reference range is 60-190 pg/mL (Quest Estrogen, 2023). Levels above this range are consistent with hyperestrogenemia. See figure 6.





**Figure 6.**

137. There are medical conditions which can result in hyperestrogenemia. For example, “[t]he concentration of estrogen in cirrhotic patients is thought to increase by fourfold compared to individuals without cirrhosis” (Pagadala, 2023). Certain rare tumors for example of the adrenal gland can result in estrogen levels 3 to 10-fold higher than normal (Cavlan, 2010).

138. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. The Endocrine Society guideline for treating gender dysphoria recommends raising estradiol levels to 2 to 43 times above the normal range.<sup>15</sup> The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. I evaluate and treat patients with gynecomastia. I have prescribed medication and have referred patients for surgery for this condition.

139. Other changes of secondary sex characteristics may develop because of hyperestrogenemia such as softening of the skin and changes in fat deposition and muscle development.

140. Long-term consequences of hyperestrogenemia include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also “[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism<sup>16</sup> over 5 fold” (Irwig, 2018).

<sup>15</sup> Estradiol is a type of estrogen. The Endocrine Society Guideline recommends raising estradiol levels to 100-200 pg/mL (Hembree, 2017). The normal adult male estradiol range is 7.7-42.6 pg/mL (Labcorp Estradiol, 2023).

<sup>16</sup> Venous thromboembolism is a blood clot that develops in a deep vein and “can cause serious illness, disability, and in some cases, death” (CDC, 2022).

141. Breast cancer is a relatively uncommon problem of the male. However, the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel et al., 2019).

142. Sexual dysfunction, including decreased sexual desire and decreased spontaneous erections, is another adverse effect of hyperestrogenemia (Hembree, 2017).

#### **D. Surgeries**

143. The fourth stage of gender affirmative therapy is surgical alterations of the body of various kinds in an attempt to somehow mimic features of the opposite sex. Although endocrinologists do not typically perform surgery, we do refer patients for surgeries and need to be aware of the risks, benefits, complications, and long-term outcomes.

144. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

145. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ, or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases an unhealthy body part is surgically removed in order to restore health.

146. In some cases a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

147. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot de novo create new organs. If a person's kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

148. There are a variety of gender affirming surgeries for females. These may include mastectomies, metoidioplasty, and phalloplasty.

##### **1. Mastectomy**

149. Mastectomies are the surgical removal of the breasts. The procedure is used in GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent loss of

the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to widening and thickening due to the stresses of breathing and arm movement. Other potential complications include the loss of normal nipple sensation and difficulties with wound healing (American Cancer Society, 2022).

150. It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery, 2022).

151. Another important consideration is that compared to the removal of an unhealthy gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and there is no organic disease process such as a cancer warranting their removal.

## **2. GAT Surgeries on the Male**

152. GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina; that procedure is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

153. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

## **3. GAT Surgeries of the Female Pelvis and Genitalia**

154. Other types of surgery for females include those of the genitalia and reproductive tract. For example, the ovaries, uterus, fallopian tubes, cervix and the vagina may be surgically removed. Removal of the ovaries results in sterilization.

155. Importantly, removing female body parts does not produce a male. Rather, the female has had sex-specific organs permanently destroyed with no hope of replacement, while remaining biologically female.

156. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which

allow for erection, therefore erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

157. Complications may include urinary stricture, problems with blood supply to the transplanted roll of tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the clitoris (Mayo Clinic, Masculinizing Surgery, 2022). A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4% (Wang, 2022).

### **III. The Lack of Evidence Supporting Gender-Affirming Therapy**

158. There is not a medical consensus supporting the use of puberty blockers and cross-sex hormones for the treatment of gender dysphoria. In my opinion, there is insufficient evidence to conclude that any benefit of such treatment would outweigh the harm, particularly given the evidence of a rapid rise in cases of youth gender dysphoria, the high rates of coexisting mental health comorbidities, and naturally high rates of desistance.

#### **A. The Endocrine Society and WPATH**

159. Clinical guidelines promoting GAT have been produced by medical organizations such as the Endocrine Society and social-political advocacy groups like WPATH. Here I discuss the Endocrine Society. I discuss the advocacy group WPATH's guidelines in a supplemental report.

##### **1. Endocrine Society**

160. In 2017 the Endocrine Society published its guideline titled the "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". It is notable that the Endocrine Society never claimed that its guideline should be considered a standard of care. In fact, quite the opposite. The Endocrine Society states that its "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care" (Hembree et al, 2017, p. 3895, emphasis added).

161. It is also notable that nine out of ten authors of the Endocrine Society Guideline were members of WPATH or worked on WPATH's scientific committees. According to

WPATH's website, seven of those nine had at some time been in WPATH leadership, including the WPATH presidency and board of directors.

162. With respect to the Endocrine Society's guideline, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence". "The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies" (Laidlaw et al., 2019).

163. Unlike some other recommendations for adolescent GAT, the Endocrine Society's guideline does not include any grading of the quality of evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for adolescent mastectomy or other surgeries.

164. Endocrinologists William Malone and Paul Hruz and other colleagues have written critically of the Endocrine Society's guideline: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence, and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological well-being. Lastly, the claim of relative safety of these interventions ignores the growing body of evidence of adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret" (Malone et al., 2021) (footnotes omitted).

165. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines" (McCartney et al., 2022). It wrote: "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) The document relates that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). It follows that the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence were not all recommendations "based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection,

and evidence summaries.” Furthermore, these ESG 2017 were highly subject to conflicts of interest. Nine out of the ten authors were members or worked on the scientific committees of the advocacy group WPATH. Additionally, WPATH was a cosponsoring organization of the 2017 Guideline. The “Enhancing Trustworthiness” article recommends the opposite composition of authors for guidelines: “A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]” (McCartney et al., 2022).

166. Further problems with the Endocrine Society’s guideline are highlighted in a recent BMJ Investigation article. It reads: “Guyatt, who co-developed GRADE, found ‘serious problems’ with the Endocrine Society guidelines, noting that the systematic reviews didn’t look at the effect of the interventions on gender dysphoria itself, arguably ‘the most important outcome.’ He also noted that the Endocrine Society had at times paired strong recommendations—phrased as ‘we recommend’—with weak evidence. In the adolescent section, the weaker phrasing ‘we suggest’ is used for pubertal hormone suppression when children ‘first exhibit physical changes of puberty’; however, the stronger phrasing is used to ‘recommend’ GnRHa treatment. ‘GRADE discourages strong recommendations with low or very low-quality evidence except under very specific circumstances,’ Guyatt told the BMJ. Those exceptions are ‘very few and far between’” (Block, 2023).

167. It is clear that with respect to the subject of gender dysphoria, the Endocrine Society has acted as a vassal organization of WPATH’s social-political advocacy group rather than an independent medical society generating its own scientific opinions. In my opinion, the Endocrine Society’s guidelines do not provide a standard of care that any physician should follow.

#### **B. Flawed Studies Based on the Problematic 2015 US Transgender Survey**

168. There is much additional evidence that questions the long-term benefits of opposite sex hormones and gender reassignment surgery and in fact suggests serious harms.

169. D’Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled “Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation” (Turban, 2020). They write in their critique of the USTS that it is “a convenience sampling, a methodology which generates low-quality, unreliable data. Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to ‘pledge’ to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample...Their analysis is compromised

by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status" (D'Angelo et al., 2021) (footnotes omitted). They also state that "[s]igmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress") (Id.).

170. Other published studies of GAT have been shown to have serious errors. For example, a major correction was issued by the American Journal of Psychiatry. The authors and editors of a 2020 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors including myself led to a reanalysis of the data and a corrected conclusion stating that in fact the data showed no improvement in mental health for transgender identified individuals after surgical treatment nor was there improvement with opposite sex hormones ("Correction", 2020; Van Mol et al., 2020).

171. The initial reports of this study claimed that the authors found treatment benefits with surgery, and this was shared widely in the media. For example, ABC News posted an article titled "Transgender surgery linked with better long-term mental health, study shows" (Weitzer, 2019). An NBC news/Reuters headline reads: "Sex-reassignment surgery yields long-term mental health benefits, study finds" (Reuters, 2019).

172. However, after twelve authors from around the world (including our team) investigated the study in detail, a number of serious errors were exposed leading to a retraction (Kalin, 2020; Anckarsäter et al., 2020).

173. In our letter to the editor, which I co-wrote with former Chairman of Psychiatry at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the original Bränström report when compared to the previous body of knowledge yielded from the Swedish Dhejne study. We wrote that "[t]he study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion" (Van Mol, Laidlaw, et al., 2020).

174. In another letter, Professor Mikael Landén wrote that "the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with



high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes” (Landen, 2020).

175. In another letter to the editor, psychiatrist David Curtis noted that “[t]he study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery” (Curtis, 2020).

176. In yet another critical letter, Dr. Agnes Wold stated that “[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria” (Wold, 2020).

#### **D. High Rates of Completed Suicide and Psychiatric Complications in GAT**

177. The most comprehensive study of GAT of its kind is from Sweden in 2011. The authors examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden.

178. The study published by Chen and Olson-Kennedy et al. confirms the inherent danger of gender affirmative therapy found in the Dhejne study. The New England Journal of Medicine published “Psychosocial Functioning in Transgender Youth after 2 Years of Hormones,” for which Dr. Johanna Olson-Kennedy is the principal investigator (Chen, Olson-Kennedy, et al., 2023). This arm of her study included 315 adolescents aged 12 to 20 years old who were taking high dose hormones of the opposite sex. The study was not randomized and had no control group. The authors report that 2 out 315 subjects died by suicide. The authors also report “The most common adverse event was suicidal ideation” in 11 subjects.



179. The death by suicide of 2 out of 315 subjects equates to approximately 317 suicide deaths per 100,000 patient-years. If we compare this figure to that of the UK's largest gender identity service, Tavistock, the "annual suicide rate is calculated as 13 per 100,000" patient-years (Biggs, 2021). The death-by-suicide rate was approximately 24 times higher in Dr. Olson-Kennedy's study compared to the much larger Tavistock Clinic. In fact, Professor Biggs reports that two of the four suicide deaths from the Tavistock data were of patients who were on the waiting list and "would not have obtained treatment" (Id.). This strongly suggests that the use of high dose opposite sex hormones in Dr. Olson-Kennedy's study was associated with a much higher death rate. NIH produced the consent forms related to this study pursuant to a FOIA request my colleague submitted. I have reviewed them and provided them to counsel for the Intervenor-Defendants. Unfortunately, of the many side effects of hormone therapy listed on the study's consent forms, death by suicide (or by any cause) is not listed and was not disclosed to participants.

180. Unfortunately, unlike the Dhejne study, the Olson-Kennedy study provides little other useful data about outcomes such as psychiatric hospitalizations, suicide attempts, or rates of comorbid psychiatric illness. These facts would be useful to know to determine how high-dose opposite hormones and gender affirmative therapy affect overall health and their association with death by suicide. All of the data collected to date in Dr. Olson-Kennedy's publicly funded study "The Impact of Early Medical Treatment in Transgender Youth" should be released to the public so that other researchers and clinicians can determine how puberty blockers, opposite sex hormones, and mastectomy surgeries affect adolescent physical and mental health.

181. While it is true that patients suffering from gender dysphoria have higher rates of suicidal ideation and completed suicide than the general population, studies have not shown that providing hormones reduces rates of suicide, and in fact those interventions may be associated with increased rates.

#### **E. An Increase in Cases of Gender Dysphoria**

182. Gender Dysphoria has been a relatively rare condition in children and adolescents. However there have been very significant increases in referrals for this condition noted around the globe.

183. For example, in the UK, "The number of referrals to GIDS [Gender Identity Development Service] has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519" (Bell v Tavistock Judgment, 2020).

There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

184. The French National Academy of Medicine wrote recently: “Parents addressing their children’s questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence” (SEGM, 2022).

185. In “a study of the Finnish gender identity service, ‘75% of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria’ (Kaltiala-Heino, 2015). In fact, ‘68% had their first contact with psychiatric services due to other reasons than gender identity issues.’ The same study also showed that 26% percent had an autistic spectrum disorder and that a disproportionate number of females (87%) were presenting to the gender clinics compared to the past” (Laidlaw in gdworkinggroup.org, 2018).

#### **F. Desistance**

186. Desistance is a term indicating that the child, adolescent, or adult who initially presented with gender incongruence has come to experience a realignment of their internal sense of gender and their physical body. “Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric” (Laidlaw et al., 2019; Ristori & Steensma, 2016).

187. Because there is no physical marker to diagnose gender dysphoria, and because it is not possible to predict which child or adolescent will desist, it is not possible to know which young person will remain transgender identified as adults. Also, because the rate of desistance is so high, gender affirmative therapy will necessarily cause serious and irreversible harm to many children and adolescents who would naturally outgrow the condition if not affirmed.

188. Puberty, which pertains to the physical development of the reproductive tract, breasts, and associated secondary sex characteristics, can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved adolescents and children aged twelve and under. For example, table 1 in Ristori and Steensma 2016 shows multiple studies involving minors. For the three most recent—Singh (2012), Wallien & Cohen-Kettenis (2008),

and Drummond et al. (2008)—these involved age ranges from 3 to 12 years old<sup>17</sup>. The desistance rate varied from 61 to 88%. Since the upper age was twelve this would include children in the age range of 8-12 years old, many of whom were already adolescents going through puberty based on a knowledge of the ages of initiation of puberty and were therefore not pre-pubertal.<sup>18</sup> Therefore we can see that a high proportion of adolescents do in fact desist.

### **G. Mastectomy Surgery for Minors**

189. Any serious look at long-term effects of surgical treatment would follow subjects out at least ten years. For example, a study was published examining patients who had mild calcium disorders due to a gland called the parathyroid. They compared a group of patients who had surgical removal of the parathyroid to a control group who had not. They examined data ten years after surgery was completed and concluded that parathyroid surgery in this group “did not appear to reduce morbidity or mortality” in that patient group (Pretorius, 2022).

190. To my knowledge there exists no comparable studies of minors with gender dysphoria comparing those who had mastectomy surgery to a control group who had not. There are also no known studies of minors followed for 10 years or more to determine the long-term risks and benefits of mastectomy for gender dysphoria.

191. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. For example, there is a study titled “Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts” (Olson-Kennedy, 2018). The study authors conclude that “[c]hest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.” However, there are a

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<sup>17</sup> “This study provided information on the natural histories of 25 girls with gender identity disorder (GID). Standardized assessment data in childhood (mean age, 8.88 years; range, 3-12 years)” (Drummond et al., 2008). “We studied 77 children who had been referred in childhood to our clinic because of gender dysphoria (59 boys, 18 girls; mean age 8.4 years, age range 5-12 years)” (Wallien et al., 2008). “Standardized assessment data in childhood (mean age, 7.49 years; range, 3–12 years) and at follow-up (mean age, 20.58 years; range, 13–39 years) were used to evaluate gender identity and sexual orientation outcome. At follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria” (Singh, 2012).

<sup>18</sup> To my knowledge the desistance literature does not examine Tanner stages of puberty as part of their studies. However, one can infer based on the ages that many children had at least begun puberty (Tanner stage 2) or were at a more advanced stage of puberty.

number of problems with this study. First, the term “chest dysphoria” is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the “chest dysphoria scale” is a measuring tool created by the authors, but which the authors state “is not yet validated.” (*Id.*, p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

192. There exists another poorly designed study which suffers from similar methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years (Mehringer, 2021). The follow up time after surgery was only 19 months and no data is provided or analyzed about key psychiatric information such as comorbid psychological illnesses, self-harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

193. Information returned from the study surveys were all qualitative and included responses such as “[My chest dysphoria] made me feel like shit, honestly. It made me suicidal. I would have breakdowns”. Another respondent stated, “I’ve been suicidal quite a few times over just looking at myself in the mirror and seeing [my chest]. That’s not something that I should have been born with” (Mehringer, 2021). The omission of psychiatric data is a major flaw in the study and also irresponsible given the obviously dangerous psychological states that some of these young people were in.

194. Since such a high proportion of subjects were using testosterone (83%), some of the responses could be attributed to adverse effects of testosterone. For example, as related earlier, high dose testosterone can manifest in irritability and aggressiveness. One study subject responded, “I get tingly and stuff and it kind of makes me want to punch something” (Mehringer, 2022).

195. The testosterone labeling also indicates nausea and depression as adverse reactions which are described by another study subject “There’s a feeling of hopelessness, of desperation, of—almost makes me feel physically sick” (Actavis Pharma, Inc., 2018; Mehringer, 2022).

196. The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit: “These findings...underscore the importance of

insurance coverage not being restricted by age” (Mehrniger, 2021). This also appears to be part of the aim of the flawed Olson-Kennedy study, which stated that “changes in clinical practice and in insurance plans’ requirements for youth with gender dysphoria who are seeking surgery seem essential” (Olson-Kennedy, 2018). So these two studies, rather than being a thorough examination of the psychological and physical risks and benefits of mastectomy surgery over the long-term appear instead to exist, at least in part, to validate the need for insurance companies to insure the costs of these dubious procedures for minors.

#### **H. Centers for Medicare and Medicaid Services**

197. The Centers for Medicare and Medicaid Services (“CMS”) has found “inconclusive” clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: “The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population” (CMS.gov, 2016).

#### **I. Nations and States Question and Reverse Course on GAT**

198. Numerous nations are questioning and reversing course on the WPATH/Endocrine Society’s low quality gender affirmative therapy guidelines. For example, in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers in GAT, the court concluded that “there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment” (*Bell v. Tavistock* Judgment, 2020, emphasis added). The case was appealed and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments.

199. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write, “As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive,

exploratory approach with gender-questioning patients should not be considered conversion therapy“ (Griffin et al., 2021).

200. In 2020, Finland recognized that “[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited,” and recommended prioritizing psychotherapy for gender dysphoria and mental health comorbidities over medical gender affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, “[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors”.

201. In 2021, Sweden’s largest adolescent gender clinic announced that it would no longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical trials (SEGM, 2021). “In December 2019, the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years. These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to assess the risk / benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments” (Gauffen and Norgren, 2021).

202. In the nation of Norway, a report from the Norwegian Healthcare Investigation Board (Ukom) was released in March of this year. The report found “there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare. Ukom defines such treatments as utprøvende behandling, or ‘treatments under trial,’ said Moen” (Block, “Norway”, 2023).

203. Dr Hilary Cass “was appointed by NHS England and NHS Improvement to chair the Independent Review of Gender Identity Services for children and young people in late 2020” (The Cass Review website, 2022). In her interim report dated February 2022, it states that “[e]vidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally” (Cass, 2022). This led to the shutting down of their Tavistock child gender identity clinic.

204. In April 2024, the “Independent review of gender identity services for children and young people: Final report”, commissioned by NHS England, was published. With respect to

comorbid psychological morbidities and distress in gender dysphoria, they recommend that “[s]tandard evidence based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and cooccurring conditions” (Cass, 2024, p. 31). With respect to puberty blocking medication they opine that “[t]he rationale for early puberty suppression remains unclear, with weak evidence regarding the impact on gender dysphoria, mental or psychosocial health. The effect on cognitive and psychosexual development remains unknown.” (Cass Final Report Web Page, 2024) With regards to opposite sex hormones for the treatment of youth gender dysphoria they state that “[t]he use of masculinising / feminising hormones in those under the age of 18 also presents many unknowns...The lack of long-term follow-up data on those commencing treatment at an earlier age means we have inadequate information about the range of outcomes for this group.” (Id) The final Cass report leaves unchanged the recommendation that surgical treatments for gender dysphoria are reserved for those eighteen years of age or older (Cass, 2024, p. 166).

205. These recent decisions by the medical authorities of other nations demonstrate that a number have reversed course and reduced or eliminated their reliance on the low-quality gender affirmative therapy guidelines put forth by WPATH and the Endocrine Society.

## **VI. Conclusion**

206. The gender affirmative therapy model suffers from serious deficiencies in logic and lacks scientific foundation. The deep error hidden in this model is that one cannot in fact change sex. One cannot acquire the deep characteristics of biological sex in order to gain the complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

207. Children and adolescents are of such immature minds that they are likely to believe that it is possible. In fact they may come to believe that their inherent, biologically necessary puberty is “terrifying” or needs to be stopped. Social transition serves to convince the child or adolescent that they can be the opposite sex. Puberty blockers sustain this state of mind by retaining a childlike state with respect to the genitalia and body habitus. High dose opposite sex hormones then cause medical conditions such as hirsutism and irreversible damage to the vocal cords in females and gynecomastia in males. These conditions serve to convince the young person that they are going through puberty of the opposite sex when in fact they are not developing sexually and are likely infertile.



208. There are known risks from GAT for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent (or assent) to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist.

209. WPATH's SOC 8 should not be followed by any physician, mental health care provider, or other medical professional.

210. For the reasons set forth above and in my supplemental report, in my professional opinion as an endocrinologist, no child or adolescent should receive puberty blockers to block normal puberty, nor should they receive supraphysiologic doses of opposite sex hormones to attempt to alter secondary sex characteristics, nor should they have surgeries to remove or alter the breasts, genitalia or reproductive tracts as part of GAT. There exists insufficient evidence of benefit, but serious concerns for risk of harm. Therefore, I believe that North Carolina's House Bill 808 is based on sound medical principles for the protection of minors.

Executed 06/02/2024

A handwritten signature in black ink that reads "Michael K Laidlaw MD". The signature is written in a cursive, flowing style.

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Michael K. Laidlaw, M.D.



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